

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/683,952	SHERRILL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael C. Henry	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/21/05.
2. ☒ The allowed claim(s) is/are 1, 4-8, 15, 16, 22-24. These claims are renumbered 1-11, respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 10/21/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
 SHAOJIA ANNA JIANG, PH.D.  
 SUPERVISORY PATENT EXAMINER

***REASONS FOR ALLOWANCE***

The following is an examiner's statement of reasons for allowance: The examiner has found claims 1, 4-8, 15, 16, 22-24 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates to a pharmaceutical composition comprising an epothilone together with a pharmaceutically acceptable carrier comprising specific concentration ranges of water, ethanol and polyoxyethylene sorbitan monooleate, wherein the composition comprises at least one cyclodextrin, and wherein the epothilone has a dosage level of specific  $\text{mg/m}^2$ ; and a method for preparing the same. The relevant prior art document (US 6,194, 181 B1) to this invention discloses a composition comprising an epothilone and  $\beta$ -cyclodextrin in a culture media. However, though both compositions comprise epothilone, applicant's composition is different to that of the prior art document in terms of the ingredients or components and concentrations and these differences are unobvious and not suggested in the prior art document. For example, the prior art document does not contain or suggest a pharmaceutically acceptable carrier comprising polyoxyethylene sorbitan monooleate, ethanol and water, much less the recited specific concentrations of the claimed compounds together with epothilone at said specific dosage level. Also, the method of preparation is different and unobvious to those of the prior art. More specifically, the prior art document prepares their epothilone composition (culture media) by the fermentation of a microorganism.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang, Ph.D can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

Michael C. Henry

  
Shaojia Anna Jiang, Ph.D.  
Supervisory Patent Examiner  
Art Unit 1623

April 11, 2006.